(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 May 2002 (02.05.2002)

PCT

(10) International Publication Number
WO 02/34143 A1

(51) International Patent Classification[7]: A61B 17/11

(21) International Application Number: PCT/GB01/04666

(22) International Filing Date: 19 October 2001 (19.10.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0026236.0 26 October 2000 (26.10.2000) GB

(71) Applicant *(for all designated States except US)*: **ANSON MEDICAL LIMITED** [GB/GB]; The Innovation Centre, 67 Milton Park, Abingdon, Oxon OX14 4RX (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HOPKINSON, Brian, Ridley** [GB/GB]; 18 Victoria Crescent, Sherwood, Nottingham NG5 4DA (GB). **KEEBLE, Duncan** [GB/GB]; c/o The Innovation Centre, 67 Milton Park, Abingdon OX14 4RX (GB).

(74) Agent: **TOLLETT, Ian**; Williams, Powell & Associates, 4 St. Paul's Churchyard, London EC4M 8AY (GB).

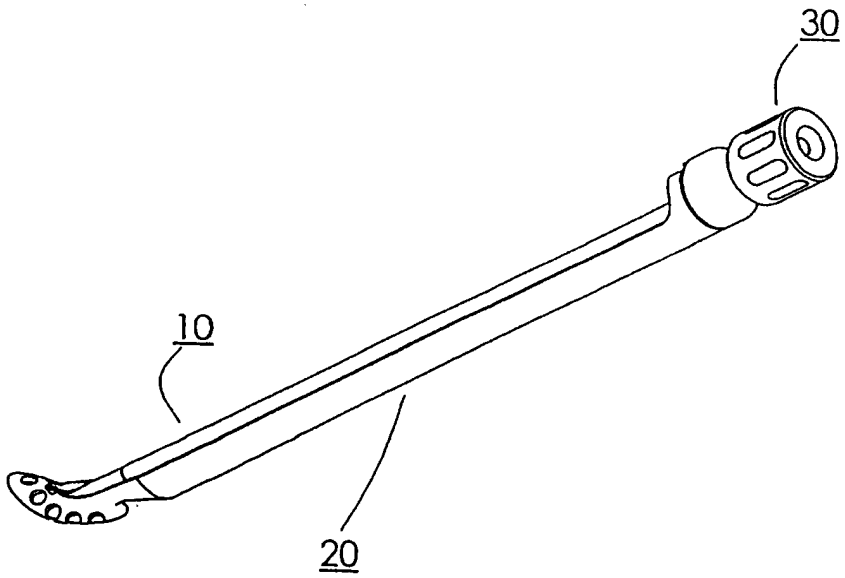
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INSTRUMENT FOR POSITIONING AN ARTERIAL GRAFT



(57) Abstract: Apparatus is provided for carrying out an end-to-side anastomosis by sealing an arteriotomy and connecting a graft (40) to the artery (50) around the arteriotomy with the seal (1) in place. The apparatus comprises means (10) for sealing the hole and means (20) for locating the graft on the outside of the wall. Once the graft is completely connected, the seal can be removed from the artery through the bore of the graft. Means may be provided for campling the graft and seal in place whilst the graft is being connected to free both of the surgeon's hands for the connection operation.

WO 02/34143 A1

INSTRUMENT FOR POSITIONING AN ARTERIAL GRAFT

This invention relates to apparatus for locating a tubular graft on a hole in the wall of an artery prior to attachment of the graft to the wall, and in particular prior to joining an artery or vascular graft to the side of an existing vessel (an end-to-side anastomosis) as part of a surgical procedure.

Joining arteries to other arteries, connecting harvested veins to arteries or connecting synthetic vascular grafts to arteries are common procedures carried out by vascular surgeons. For example, in coronary artery by-pass surgery a vein, often the saphenous vein from the leg of the patient, is connected to the side of a coronary artery at two points in order to by-pass a narrowing in that artery. Another example of bypassing carried out with an anastomosis between a graft and an artery occurs in abdominal aortic surgery when a graft from the aorta is joined to one iliac artery, excluding blood supply to the iliac of the other leg. Blood supply is restored to this, contralateral, leg by connecting a graft between the femoral arteries of either leg.

The grafting described above is usually carried out by means of open surgical techniques and the physical connection is made between the vessels by suturing the end of one vessel to the side of another.

The conventional procedure requires experience and dexterity to carry out and can take a significant amount of surgical time. The duration of the procedure is important in all cases, but in the coronary arteries, there are severe time constraints limiting the period for which the heart can be stopped and surgery can take place.

WO 98/52475 (Cardio Medical Solutions) discloses a device for facilitating end-to-side anastomosis comprising a shaft with a collapsible "umbrella-like" seal at one end. The seal can be collapsed, inserted through an arteriotomy, and then opened to form an internal seal for the arteriotomy. A graft can then be partially sutured to the artery

The major disadvantage of this method is that the graft must be loosely connected to the artery in order to allow removal of the seal, which may therefore result in leakage from the artery. Also, the seal is an internal one only, and must be flexible, which means that it cannot provide any support for the suturing process. Finally, in order to maintain the seal, the surgeon must pull the shaft towards him away from the artery, which uses one of his hands and restricts the ease of the suturing procedure.

EP 0,895,753 (Academisch Ziekenhuis Utrecht) discloses a similar system to the Cardio Medical Solutions system described above, in which a flexible internal seal is used to reduce loss of blood from an arteriotomy whilst a graft is being partially sutured around the arteriotomy. It has the same disadvantages as the solution described above, in that the graft cannot be completely connected to the artery because the seal must be removed before a complete connection is made. Also, the seal must be held in place by the surgeon during the suturing procedure.

US 6,068,637 (Cedar Sinai Medical Centre) discloses a wholly intra-lumenal support which cannot seal the arteriotomy completely. Moreover, it must be removed from the bore of the lumen rather than through the arteriotomy or the exterior of the graft.

EP 0,856,287 (Cardio Thoracic Systems, Inc.) discloses a perfusion device for maintaining blood flow in a vessel whilst isolating an anastomosis. This is a very complex system mechanically and again requires incomplete suturing of the graft in order to remove the seal.

In accordance with a first aspect of the present invention, there is provided apparatus for locating a tubular graft on a hole in the wall of an artery prior to attachment of the graft to the wall, comprising means for sealing said hole and means for locating the graft on the outside of the wall in order that the graft can be attached to the wall around said hole, wherein said means for sealing said hole is shaped such that it can be removed from the hole after the graft has been attached to the wall.

The advantage of the present invention lies primarily in the provision of the removable means for sealing the hole. This increases the time available to the surgeon to attach the graft to the artery, thereby enabling a better quality attachment to be performed. The means for sealing the hole is preferably shaped so that it can be left in place until after the connection between the graft and the artery wall has been made leak-free (i.e. complete attachment), after which the means for sealing the hole can be removed through the bore of the graft.

In a preferred embodiment, said means for sealing said hole comprises a plate shaped to fit through said hole in order to lie behind the wall with the plate occluding said hole. The plate preferably has a handle for urging the plate against the inside of the wall in order to seal said hole and for removing the plate from the hole after the graft has been attached to the wall.

The means for sealing said hole is preferably substantially rigid. This allows for a better seal around the hole, because the means for sealing the hole can be urged against the inside of the wall without there being a risk that said means will collapse or fold in half, as is the case with prior art devices.

In a particularly preferred embodiment, the means for sealing the hole comprises a plate shaped to fit through the hole in order to lie behind the wall with the plate occluding said hole. The plate is preferably elliptical in shape, with the preferred ratio of the major to the minor axis being from 2:1 to 4:1. This shape is particularly preferred because of the ease of withdrawing the plate from the artery.

The plate may have a handle for urging the plate against the inside of the wall in order to seal the hole and for removing the plate from the hole after the graft has been attached to the wall. In a particularly preferred embodiment, the plate and the handle are connected by means of a pivotable joint (such as a ball-and-socket joint or a hinge) to permit easy removal of the device from the artery and graft.

According to a second aspect of the present invention, there is provided apparatus for locating a tubular graft on a hole in the wall of an artery prior to attachment of the graft to the wall, comprising a plate shaped to fit through said hole in order to lie behind the wall with the plate occluding said hole, a handle for urging the plate against the inside of the wall in order to seal said hole and for removing the plate from the hole after the graft has been attached to the wall, the plate and the handle being connected by means of a pivotable joint which permits the angle between the plate and the handle to be adjusted by the user, wherein the plate is shaped such that it can be removed from the hole after the graft has been attached to the wall.

The advantage of this embodiment of the invention is that it permits a surgeon to control the angle between the graft and the artery whilst the graft is being attached to the artery, so as to yield the optimum haemodynamic performance. Any excess graft material resulting from suturing the graft at an angle to the artery can simply be cut off.

The current invention preferably comprises an instrument and a set of fixators which, when used to form an anastomosis, significantly simplify the procedure. The instruments both seal the artery during the procedure to reduce blood loss and hold the graft against the wall of the artery to allow it to be fixed in the correct place. The fixators provide mechanical attachment of the graft to the artery and a liquid seal, depending upon the numbers of fixators employed. In particular, the fixators can be applied in seconds whereas suturing can take tens of minutes.

The instrument preferably comprises two main components, one of which is intra-arterial and the another extra-arterial (although it will be seen that part of the intra-arterial component extends extra-arterially). Preferably, the two components can be releasably joined to form a single instrument or can be used in conjunction with each other without connection. The components can also be constructed in a modular way so that the instrument can be taken apart once the graft has been attached at both ends. The components may be formed from any suitable material such as a plastic material, a metal, or a combination of both.

The intra-arterial component may comprise a curved plate with rounded edges having a major and a minor axis. Preferably the plate is elliptical in shape and the curve is formed around an axis parallel to the major axis of the plate. The radius of said curvature is arranged to be approximately the same as the internal radius of the artery to which the graft is to be attached. To the plate is attached one end of a handle which has a diameter suitable to pass through the graft. Preferably, the handle makes an angle of 30° to 55°, and most preferably about 40°, to the major axis of the elliptical plate.

The second end of the handle can be adapted to engage the extra-arterial part of the instrument so that the intra-arterial part can be clamped to the extra-arterial part. Alternatively, the second end of the handle can be adapted to be held by hand.

The surface of the plate preferably has small hollows formed in it which can be used to guide the path of a fixator while it is being applied.

The extra-arterial part of the instrument preferably comprises a tube with a flange at one end. The tube is of adequate diameter for the graft to pass within. Ideally the flange at the end of the tube is curved so that it will fit snugly onto the surface of the intra-arterial plate. The flange is preferably mounted on the end of the tube at an angle which is equal to that made between the handle and the intra-arterial plate.

The flange may be perforated around its periphery, preferably with between six and twelve holes. Other variants of the design can be constructed which use one hole or multiple holes, the maximum useful number of holes being of the order of 30 for a vessel 10mm in diameter. Advantageously, the holes can be positioned so that they break through the edge of the flange. When the flange is placed over the curved plate of the intra-arterial component, holes in the flange should be positioned to align with hollows or indentations in the intra-arterial plate. Alternatively, the intra-arterial plate may be used to deflect the tips of staples back towards the artery wall after implantation.

The flange may be perforated around its periphery, preferably with between six and twelve holes. Other variants of the design can be constructed which use one hole or multiple holes, the maximum useful number of holes being of the order of 30 for a vessel 10mm in diameter. Advantageously, the holes can be positioned so that they break through the edge of the flange. When the flange is placed over the curved plate of the intra-arterial component, holes in the flange should be positioned to align with hollows or indentations in the intra-arterial plate. Alternatively, the intra-arterial plate may be used to deflect the tips of staples back towards the artery wall after implantation.

Preferably, the flange is modified to have spikes or hooks on its surface so that a graft can be passed down the inside of the tube, everted over the flange and retained on the flange by the hooks or spikes.

The tube and flange are preferably constructed in at least two parts which can split apart from around the graft. The two or more parts in such an arrangement may remain attached by a thin layer or web of the material from which the tube is made. Thus, if made from a suitable plastic, the tube can be torn apart to separate the components; this method of construction provides a solid method of retaining the components together when in use. Alternatively, the walls of the tube can be cut away to provide slots which give access to the graft, or the tube can be constructed from an open frame structure in which the cross-section of the tube is not necessarily circular or complete.

The fixators employed may be variants of staples. They can follow the common pattern employed for stapling papers in an office, or they can be adapted to follow the designs described in WO 00/07506 or WO 01/58363 (in the name of the present applicant).

Method of Use

In a third aspect of the present invention, there is provided a method for attaching a graft to the wall of an artery, comprising the steps of providing apparatus as defined above.

making a hole in the artery wall, sealing said hole, locating the graft on the outside of the wall over said hole, attaching the graft to the wall to surround said hole, and removing said means for sealing.

The graft to be attached to the artery is preferably passed through the inside of the extra-arterial component and rolled back over the outside of the flange. Where fitted, the hooks or barbs attached to the flange will hold the graft in place on the flange. This step in the method can be carried out during manufacture.

An arteriotomy, which is a single longitudinal slit in the wall of an artery, is cut and the curved elliptical plate of the intra-arterial component is passed through the arteriotomy and into the artery. The curved plate is positioned by means of its handle component to be centred under the arteriotomy and the pressure of blood within the artery will push the plate against the artery's wall and seal the arteriotomy.

The extra-arterial component, containing the pre-mounted graft, is slid over the handle of the intra-arterial component and pushed down so that, where the graft is rolled out of the tube and over the flange, its internal face is in direct contact with the wall of the artery. Ideally, a locking mechanism is fitted or used at this stage which urges the extra-arterial part against the intra-arterial part, sandwiching the artery wall and the graft between them.

Staples are pushed through the holes in the flange so that they pierce the graft and the artery wall Staples following the pattern described in WO 00/07506 or WO 01/58363 will pass through the artery wall and start to deploy. An alternative form of staple can use the reaction generated by the intra-arterial plate to cause the legs of the staple to fold and grip the artery wall. Where necessary, sutures or tissue glues can be used to reinforce the attachment between the graft and the vessel wall.

If the graft has a free end, the extra-arterial part can be removed by freeing the graft from the hooks or barbs on the flange and sliding the tube from over the graft. If the graft is attached at its distal end, the extra-arterial component can be removed by splitting it from around the graft.

If the graft has a free end, the intra-arterial component can be removed from the arteriotomy by a combination of sliding and rotation in order to withdraw it from the length of the graft. Where the graft is already attached at the distal end, the intra-arterial component can be introduced into the graft through a slit cut into the side of the graft. At the end of the procedure, the intra-arterial component can be removed from the arteriotomy in the manner just described and then removed from the graft by withdrawing it from the slit in the graft.

A specific embodiment of the present invention will now be disclosed with reference to the drawings, in which:

Figures 1 and 1A show perspective views of the intra-arterial component in accordance with the invention;

Figure 2 shows in detail the shape of the elliptical plate at one end of the intra-arterial component of Figures 1 and 1A;

Figures 3 and 4 show perspective views of the extra-arterial part of the apparatus in accordance with the invention;

Figures 5 and 6 illustrate perspective views of a locking connector for joining the intra-and extra-arterial components together;

Figures 7 and 8 depict perspective views of the complete assembly.

Figure 9 shows the complete assembly in use;

Figures 10, 11 and 12 show perspective views of the instrument in use;

Figure 13 depicts the use of the apparatus together with a hand-held stapler; and

Figure 14 is a schematic view, in cross section, of a staple which has been fixed by means of the apparatus of the present invention.

The various components of the inventive apparatus will first be described with reference to Figures 1 to 8.

Turning first to Figures 1 and 1A, intra-arterial component 10 is formed from a plastics material (or alternatively metal) and consists essentially of an elliptical intra-arterial plate 1 at the end of 190mm long handle 2. The end 3 of handle 2 distal to plate 1 is threaded to accept locking connector 30, as will be described below.

As shown in more detail in Figure 2, plate 1 is elliptical in shape with major axis 14 of about 20mm in length, minor axis 15 of about 7.5mm in length, and with a curvature 16 of approximately 120°. Plate 1 is connected to handle 2 at an angle of approximately 40°. As will be described below, this configuration of the plate 1 makes it particularly suitable for use in the inventive method.

Turning now to Figures 3 and 4, extra-arterial component 20, which is formed of a plastics material (or alternatively metal), comprises shaft 22 which is flared at one end to form flange 23. Gully 24 runs the length of shaft 22 and forms a hole through flange 23 at its centre. Flange 23 therefore forms a sort of annulus around this central hole, and is further perforated with holes 25 and cut-away sections 26 which break through the edge of flange 23.

Head 27 is formed at the end of shaft 22 distal to flange 23. Head 27 is generally circular in shape and perpendicular to the longitudinal axis of shaft 22, with a radial cut-out which is generally perpendicular to gully 24.

Figures 5 and 6 show locking connector 30 which is essentially a nut having threaded bore 31 and a ridged outer surface 32 to enable the knot to be tightened on to the threaded end 3 of intra-arterial component 10.

The assembly of intra-arterial component 10 and extra-arterial component 20 connected together by locking connector 30 is depicted in Figures 7 and 8. The two components are fitted together by inserting the end of handle 2 distal to plate 1 through the hole in the centre of flange 23, such that handle 2 is seated in gully 24 in shaft 22, with the end of handle 2 emerging through the hole in the centre of head 27. Plate 1 (not shown in Figures 7 and 8) abuts flange 23. Locking connector 30 can then be threaded onto threaded end 3 on handle 2 in order to connect components 10 and 20 together.

The use of the apparatus of the present invention to connect a graft to an artery will now be described with reference to Figures 9 to 13.

First, an incision (arteriotomy) is made in artery 50. Intra-arterial component 10 is then put in place by inserting plate 1 at an angle through the slit/incision so that it lies inside the artery behind the incision and generally parallel to the artery wall. It will be appreciated that plate 1 may need to be inclined to the incision in order that it can be passed through the incision, and this can be done very easily by the surgeon simply by manipulating the plate 1 by means of handle 2.

Graft 40 is then put in place by inserting handle 2 through the bore of graft 40 and threading the graft 40 over handle 2 until the end of graft 40 artery 50 is proximate to artery 50.

Next, extra-arterial component 20 is threaded over graft 40 and handle 2 and advanced down graft 40/handle 2 until flange 23 is at the end of handle 2 proximate plate 1.

In an alternative embodiment, graft 40 can be provided ready-installed in gully 24 of extra-arterial component 20, so that graft 40 and extra-arterial component 20 can be threaded over handle 2 together.

The arrangement shown in Figure 9 depicts the complete assembly in use to introduce graft 40 to the wall of artery 50. In the Figure, the elliptical plate 1 already lies within artery 50 and is hidden from view. For clarity, graft 40 is not shown rolled back over flange 23 but is shown flared below flange 23. This arrangement is commonly adopted with thick walled PTFE graft material. Extra-arterial component 20 is shown lightly pinching graft 40 and being advanced down handle 2.

In a preferred embodiment, intra-arterial component 10, graft 40 and extra-arterial component 20 are supplied pre-assembled as shown in Figure 10. It will be appreciated that this reduces the time needed by the surgeon, because extra-arterial component 20 is already far advanced down handle 2.

In use, therefore, the surgeon inclines plate 1 sideways and inserts it into the arteriotomy of artery 50, to result in the position shown in Figure 11, with plate 1 inside artery 50 and substantially parallel to the artery wall. Extra-arterial component 20 can then be fully advanced down handle 2, trapping the end of graft 40 between flange 23 and plate 1. The relative lengths of handle 2 and shaft 22 mean that threaded end 3 of handle 2 now emerges fully from head 27, enabling locking connector 30 to be screwed onto threaded end 3 and fully tightened, and thereby locking extra-arterial components 20 in place on intra-arterial component 10, with graft 40 being trapped between flange 23 and plate 1.

The arrangement described means that the graft can be clamped to the artery, enabling the surgeon to work on connecting/suturing the graft 40 to artery 50 without having to hold the assembly in place. The whole system therefore works as a "third hand" for the surgeon. The surgeon can then connect graft 40 to artery 50 by using for example a stapling machine 60 to affix graft 40 to artery 50 using staples 70 as shown in Figures 13 and 14 (staple 70 is the subject of co-pending PCT publication no. WO 01/58363 in the name of the present applicant).

Staple 70 can be inserted through guidance aperture 26, wherein plate 1 urges the tips of staple 70 to curl back out through the wall of artery 50.

Once the surgeon has connected graft 40 to artery 50, extra-arterial component 20 is removed from graft 40 and handle 2 is then manipulated so as to rotate plate 1 by approximately 180°, whereby it can be drawn out of artery 50 and the bore of graft 40 because of the shape of plate 1 and the angle which it makes with handle 2.

It will be appreciated that the apparatus for the present invention can be used with other fixing methods, such as suturing and/or gluing which have not been described herein. As will also be appreciated, the utility of the inventive apparatus is not limited to connecting arteries and grafts. Hence, "artery" as used herein includes any body lumen and "graft" any tubular implant.

CLAIMS

1. Apparatus for locating a tubular graft on a hole in the wall of an artery prior to attachment of the graft to the wall, comprising means for sealing said hole and means for locating the graft on the outside of the wall in order that the graft can be attached to the wall around said hole, wherein said means for sealing said hole is shaped such that it can be removed from the hole after the graft has been attached to the wall.

2. Apparatus as claimed in claim 1, wherein the means for sealing said hole is shaped such that it can be removed from the hole and through the bore of the graft after the graft has been attached to the wall.

3. Apparatus as claimed in claim 1 or 2, wherein the means for sealing said hole is substantially rigid.

4. Apparatus as claimed in any preceding claim, wherein said means for sealing said hole comprises a plate shaped to fit through said hole in order to lie behind the wall with the plate occluding said hole.

5. Apparatus as claimed in claim 4, wherein the plate is elliptical in shape.

6. Apparatus as claimed in claim 5, wherein ratio of the major axis to the minor axis is from 2:1 to 4:1.

7. Apparatus as claimed in claim 5 or 6, wherein the plate is curved in the direction of the minor axis so as to follow substantially the curvature of the inner wall of an artery.

8. Apparatus as claimed in any of claims 4 to 7, wherein the plate has a handle for urging the plate against the inside of the wall in order to seal said hole and for removing the plate from the hole after the graft has been attached to the wall.

9. Apparatus as claimed in claim 8, wherein the handle performs the functions of the means for locating the graft.

10. Apparatus as claimed in any preceding claim, wherein the means for locating the graft on the outside of the wall comprises a projection on the plate, the projection being shaped for inserting into the bore of the graft.

11. Apparatus as claimed in claim 10, wherein the projection is a shaft over which the graft can be fitted, the shaft emerging from the distal end of the graft to form a handle for the plate.

12. Apparatus as claimed in any of claims 4 to 11, additionally comprising means for pressing the graft against the plate such that the artery wall is sandwiched between the graft and the plate.

13. Apparatus as claimed in claim 12, wherein the means for pressing the graft against the plate comprises a substantially annular element having a handle.

14. Apparatus as claimed in claim 12 or 13, wherein the means for pressing the graft against the plate comprises a sleeve shaped to fit over the graft, the sleeve having a flange at one end, wherein in use the end of the graft can be trapped between the flange and the plate by pulling on the plate handle and pushing on the sleeve.

15. Apparatus as claimed in claim 14, wherein the plate and the flange are shaped to fit together in order to sandwich the graft and artery wall therebetween.

16. Apparatus as claimed in any of claims 12 to 15, additionally comprising means for lockably clamping the plate and the flange together, whereby in use the surgeon has both hands free for attaching the graft to the artery.

17. Apparatus as claimed in claim 16, wherein the end of the handle distal to the plate extends beyond the means for pressing the graft against the plate, and wherein a locking member is provided to attach to said end to prevent the means for pressing the graft against the plate from being removed from the handle.

18. Apparatus as claimed in any of claims 14 to 17, wherein the flange has a plurality of holes therein to assist in locating staples or thread for attaching the graft to the artery wall.

19. Apparatus for attaching a tubular graft to a hole in an artery wall, comprising apparatus as claimed in any preceding claim and means for attaching the graft to the wall.

20. A kit of parts, comprising apparatus for attaching a tubular graft to a hole in an artery wall as claimed in any preceding claim, and a graft or graft-stent.

21. A kit of parts as claimed in claim 20, wherein the graft is supplied pre-mounted on said apparatus.

22. A method for attaching a graft to the wall of an artery, comprising the steps of providing apparatus as claimed in any preceding claim, making a hole in the artery wall, sealing said hole, locating the graft on the outside of the wall over said hole, attaching the graft to the wall to surround said hole, and removing said means for sealing.

23. A method as claimed in claim 22, wherein the means for sealing is removed from the artery through the bore of the graft.

24. Apparatus for locating a tubular graft on a hole in the wall of an artery prior to attachment of the graft to the wall, comprising

a plate shaped to fit through said hole in order to lie behind the wall with the plate occluding said hole,

a handle for urging the plate against the inside of the wall in order to seal said hole and for removing the plate from the hole after the graft has been attached to the wall,

the plate and the handle being connected by means of a pivotable joint which permits the angle between the plate and the handle to be adjusted by the user,

wherein the plate is shaped such that it can be removed from the hole after the graft has been attached to the wall.

25. The use of apparatus as claimed in claim 24 for controlling the angle between an artery and a graft attached to the artery in an end-to-side anastomosis.

26. A method for controlling the angle between an artery and a graft attached to the artery in an end-to-side anastomosis, comprising providing apparatus as claimed in claim 24, making a hole in the artery wall, inserting the plate through the hole into the artery and pulling on the handle to seal the hole, inserting the handle through the bore of a graft so that one end of the graft lies over the hole, adjusting the angle between the handle and the plate and therefore the angle between the graft and the artery, attaching the graft to the artery around the hole, and removing the plate from the artery through the hole and the graft.

27. A method as claimed in claim 26, wherein the graft is pre-mounted on the handle.

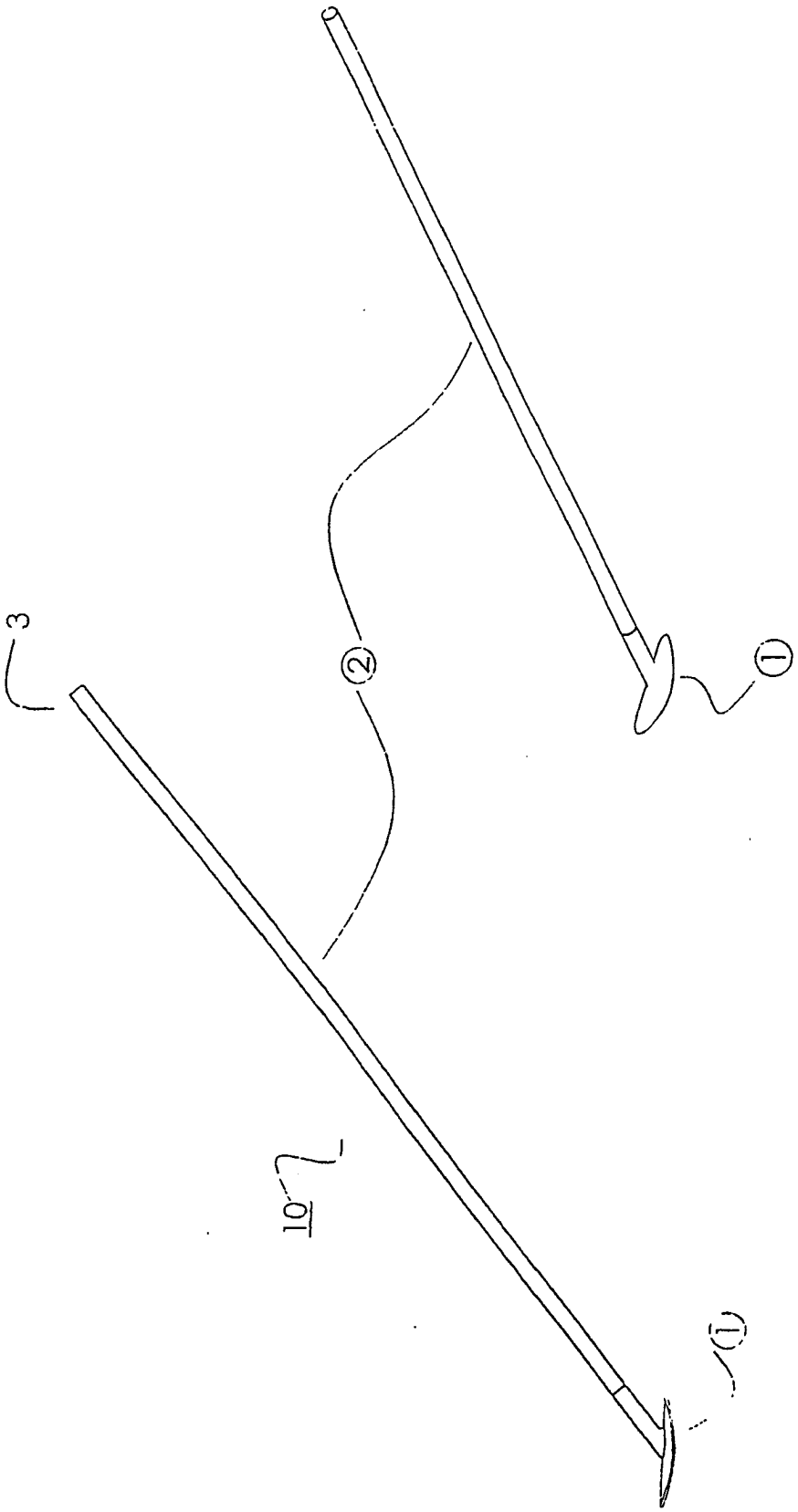


FIG 1A

FIG 1

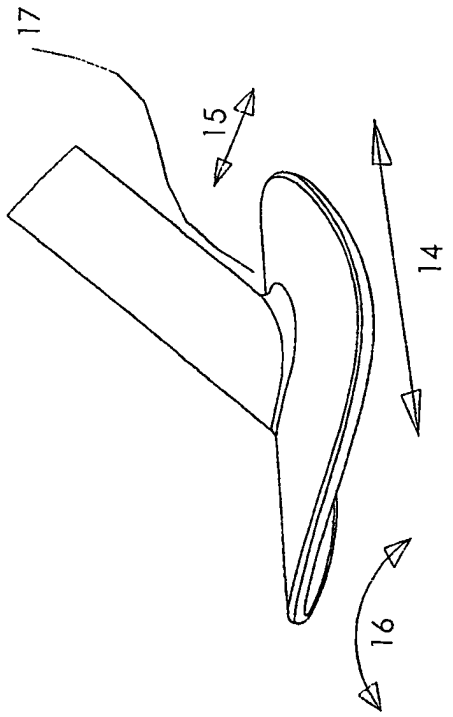


FIG 2

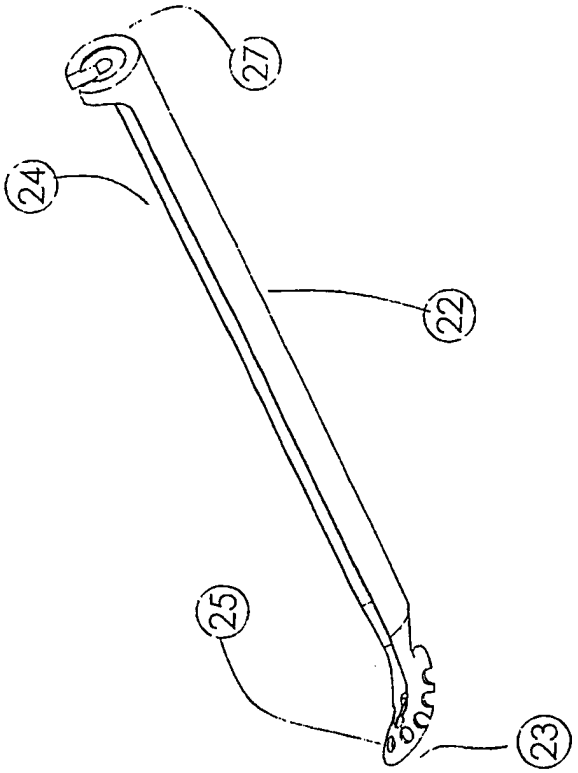


FIG 4

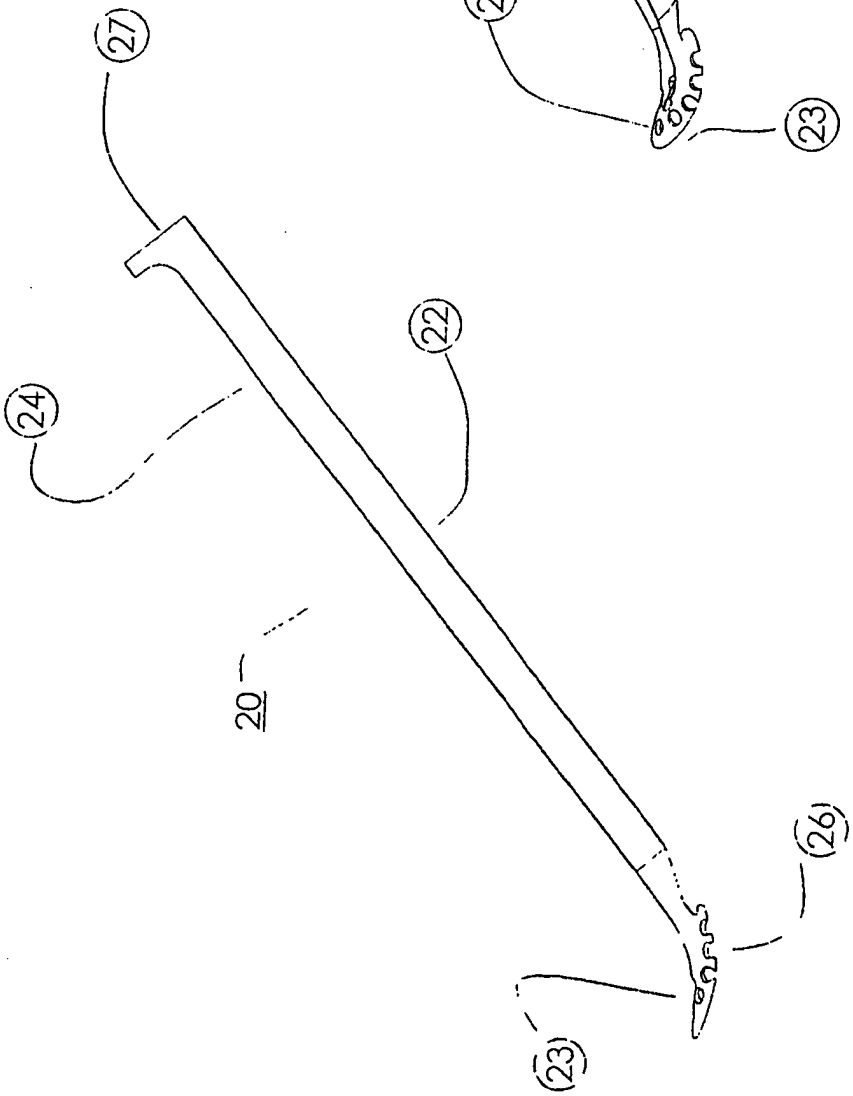


FIG 3

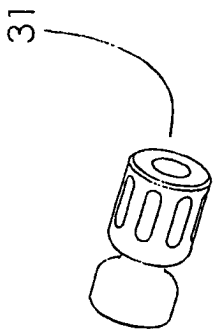


FIG 6

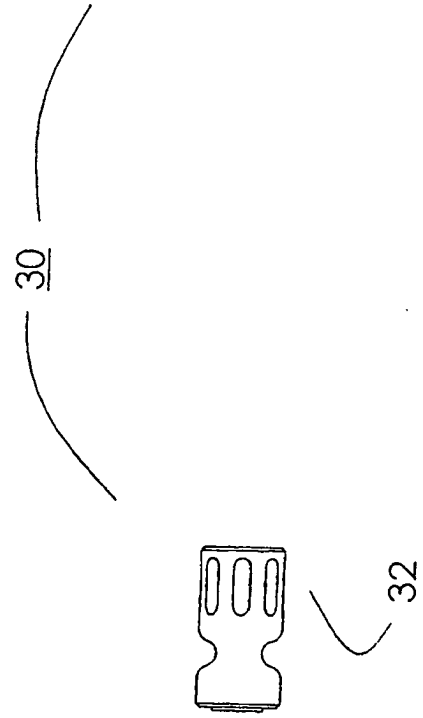


FIG 5

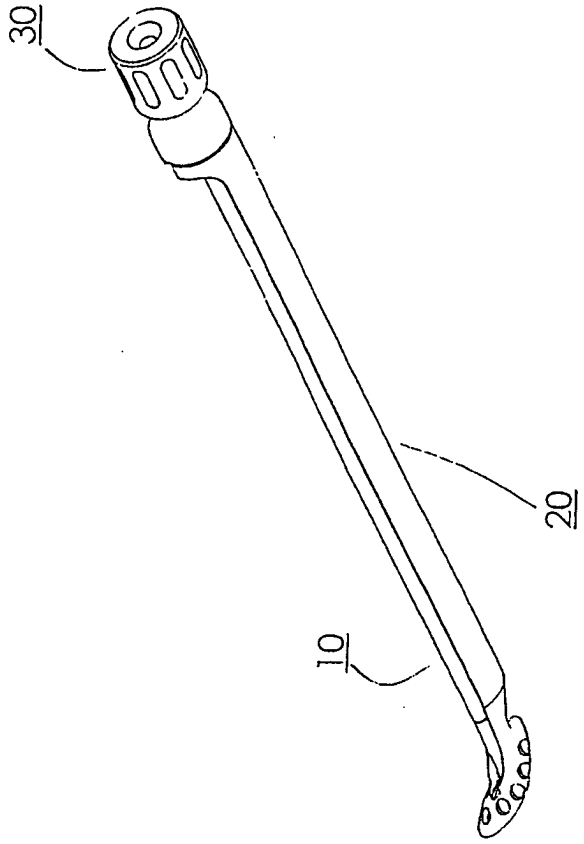


FIG 8

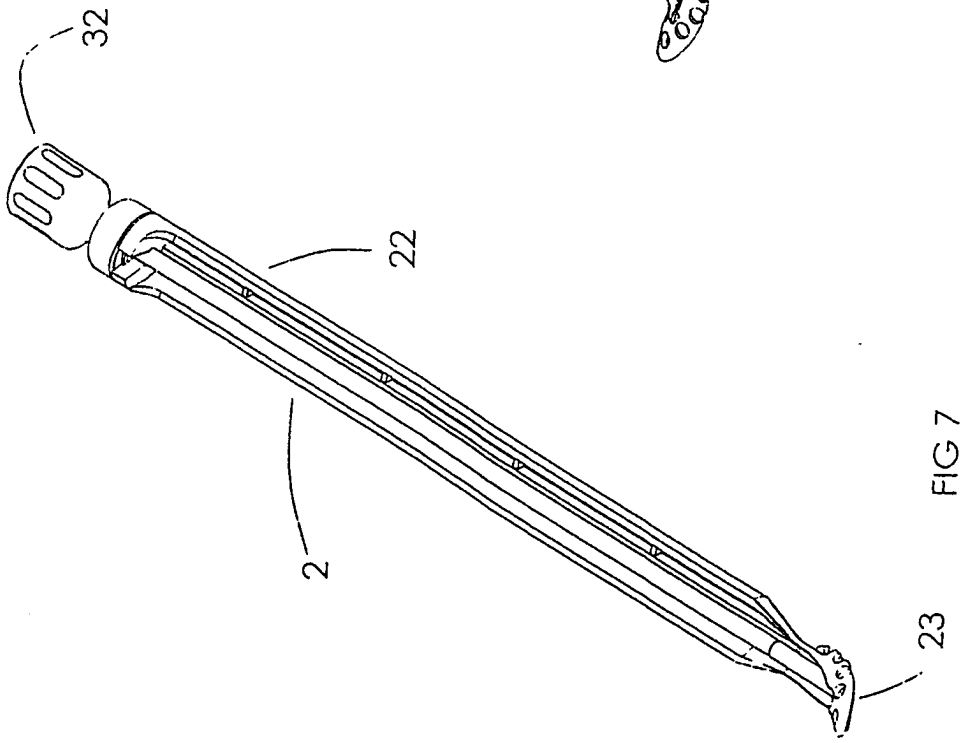


FIG 7

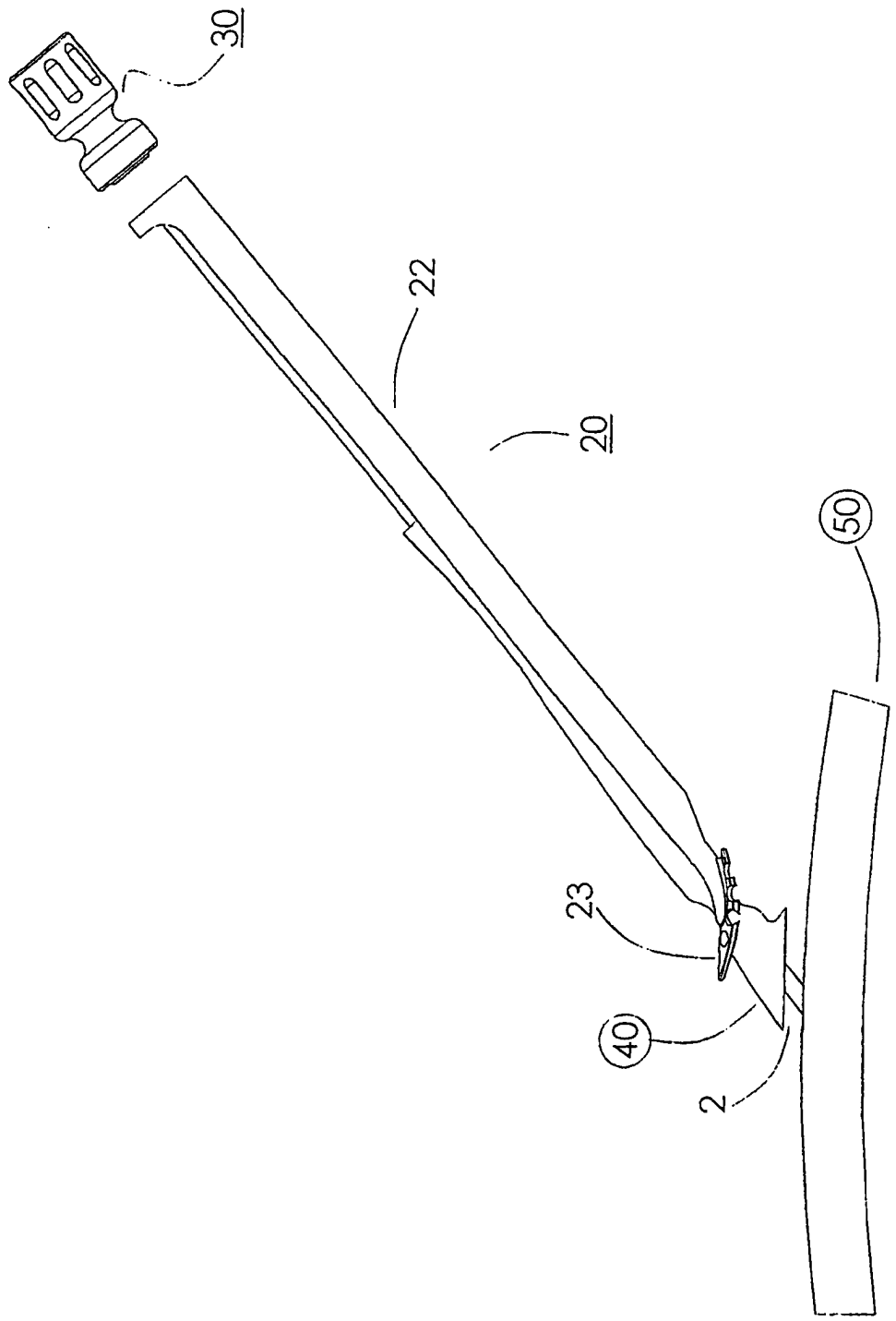


FIG 9

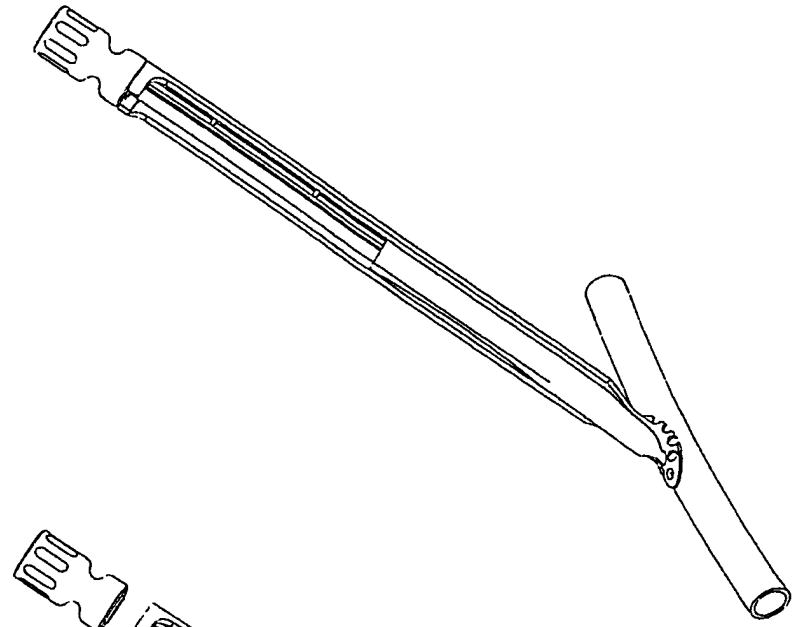


FIG 12

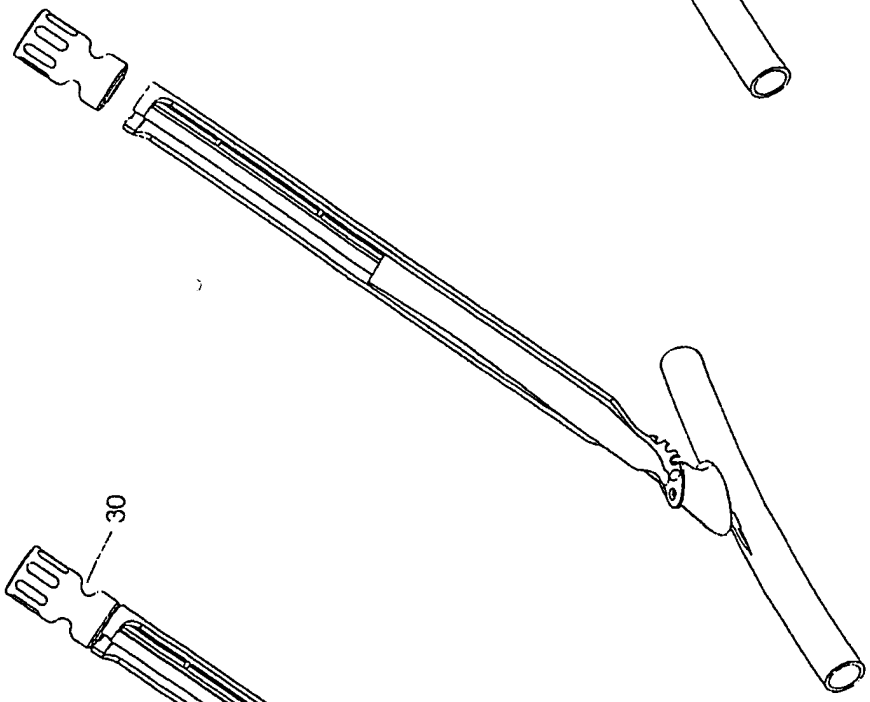


FIG 11

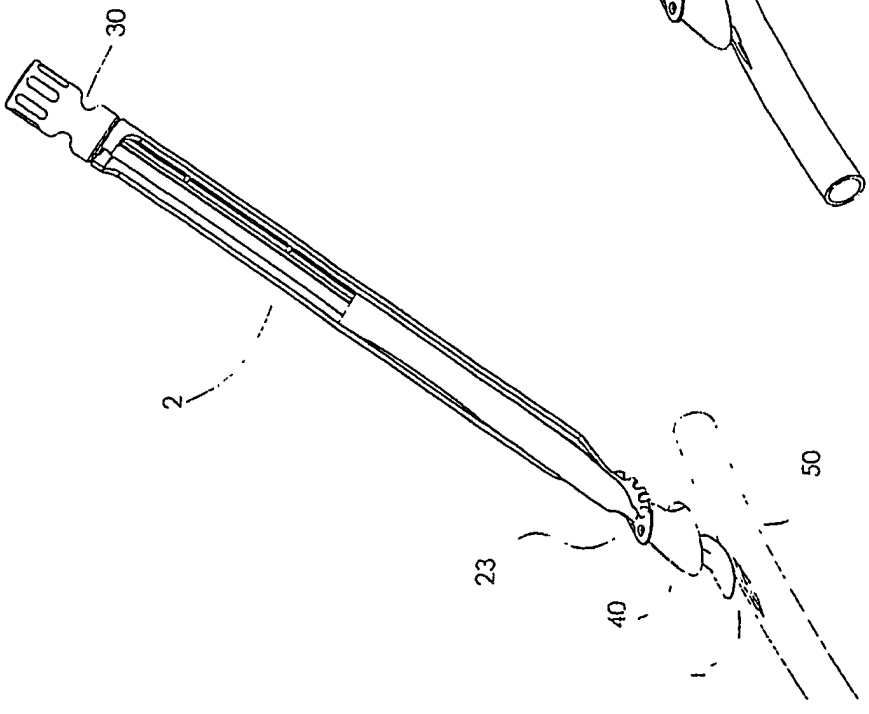


FIG 10

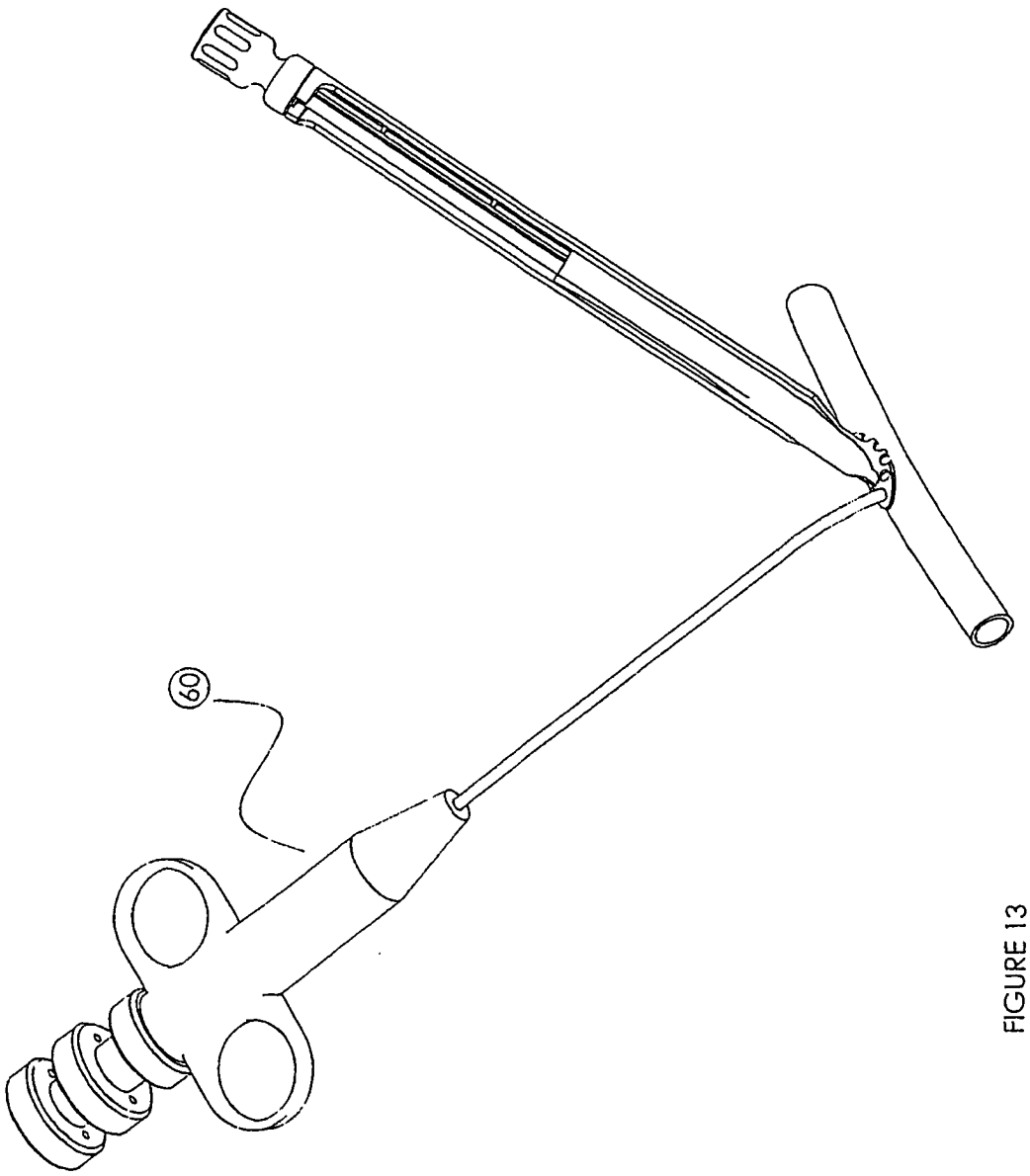


FIGURE 13

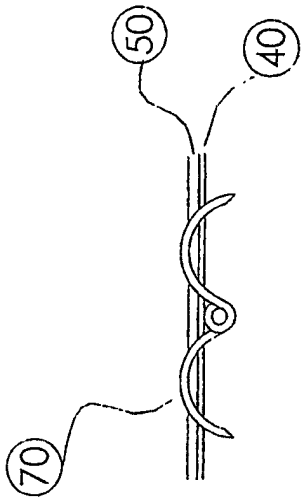


FIG 14

INTERNATIONAL SEARCH REPORT

In Application No
PCT/GB 01/04666

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	DE 196 00 519 A (PIER ARNOLD DIPL ING DR MED) 10 July 1997 (1997-07-10)	1-4, 8-10, 12-16, 19-21,24
A	abstract; claims 1-3; figures 2-2D	5-7
X	US 5 797 934 A (RYGAARD JORGEN A) 25 August 1998 (1998-08-25)	1,2,4, 8-11, 19-21
Y	abstract; figures 7-10	24
X	WO 00 59380 A (COALESCENT SURGICAL INC) 12 October 2000 (2000-10-12)	1,2, 19-21
Y	page 4, line 13 - line 29; claim 66; figures 16A-G,18A-E,19,20	3,10,11

-/--

[X] Further documents are listed in the continuation of box C

[X] Patent family members are listed in annex

* Special categories of cited documents

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 January 2002	23/01/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office P B 5818 Patentlaan 2 NL 2280 HV Rijswijk Tel (+31-70) 340 2040, Tx 31 651 epo nl, Fax (+31-70) 340-3016	Péru, L

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Ir Application No
PCT/GB 01/04666

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No
X	EP 0 895 753 A (ACADEMISCH ZIEKENHUIS UTRECHT) 10 February 1999 (1999-02-10) cited in the application column 10, line 1 - line 44; figures 1-6	1,2,4-8
Y	column 10, line 49 -column 11, line 27; figure 7	3,10,11, 24
X	WO 98 52475 A (CARDIO MEDICAL SOLUTIONS) 26 November 1998 (1998-11-26) cited in the application abstract; figures 25,26	1,2
A	US 5 456 714 A (OWEN EARL R) 10 October 1995 (1995-10-10) abstract; figures 4-6	14-17
A	EP 0 495 673 A (ETHICON INC) 22 July 1992 (1992-07-22) figure 10	17,18

INTERNATIONAL SEARCH REPORT

In Application No
PCT/GB 01/04666

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
DE 19600519	A	10-07-1997	DE	19600519 A1	10-07-1997
			WO	9724990 A1	17-07-1997
US 5797934	A	25-08-1998	DK	145593 A	24-06-1995
			AT	182454 T	15-08-1999
			AT	181808 T	15-07-1999
			AU	687807 B2	05-03-1998
			AU	6719894 A	10-07-1995
			AU	691808 B2	28-05-1998
			AU	6719994 A	10-07-1995
			CA	2179507 A1	29-06-1995
			CA	2179508 A1	29-06-1995
			DE	69419437 D1	12-08-1999
			DE	69419437 T2	28-10-1999
			DE	69419780 D1	02-09-1999
			DE	69419780 T2	13-01-2000
			WO	9517127 A1	29-06-1995
			WO	9517128 A1	29-06-1995
			DK	740531 T3	31-01-2000
			DK	774923 T3	24-01-2000
			EP	0740531 A1	06-11-1996
			EP	0774923 A1	28-05-1997
			ES	2138081 T3	01-01-2000
			ES	2137366 T3	16-12-1999
			JP	2997315 B2	11-01-2000
			JP	9503420 T	08-04-1997
			JP	2997316 B2	11-01-2000
			JP	9503421 T	08-04-1997
			KR	189276 B1	01-06-1999
			KR	189277 B1	01-06-1999
			NO	962632 A	09-08-1996
			NO	962633 A	09-08-1996
			US	5725544 A	10-03-1998
			US	5868770 A	09-02-1999
WO 0059380	A	12-10-2000	AU	4202300 A	23-10-2000
			WO	0059380 A2	12-10-2000
EP 0895753	A	10-02-1999	EP	0894475 A1	03-02-1999
			EP	0895753 A1	10-02-1999
			AU	8650498 A	08-03-1999
			EP	0999790 A1	17-05-2000
			WO	9908603 A1	25-02-1999
WO 9852475	A	26-11-1998	US	5944730 A	31-08-1999
			AU	7580398 A	11-12-1998
			EP	0983026 A1	08-03-2000
			WO	9852475 A1	26-11-1998
			US	6171319 B1	09-01-2001
US 5456714	A	10-10-1995	AT	175568 T	15-01-1999
			AU	658915 B2	04-05-1995
			WO	9300868 A1	21-01-1993
			CA	2112474 A1	21-01-1993
			DE	69228184 D1	25-02-1999
			DE	69228184 T2	16-09-1999
			EP	0593600 A1	27-04-1994
			JP	7500023 T	05-01-1995

Form PCT/ISA/210 (patent family annex) (July 1992)

INTERNATIONAL SEARCH REPORT

In Application No
PCT/GB 01/04666

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0495673 A	22-07-1992	US 5222963 A	29-06-1993
		AU 1015592 A	23-07-1992
		BR 9200118 A	06-10-1992
		CA 2059458 A1	18-07-1992
		DE 69218268 D1	24-04-1997
		DE 69218268 T2	03-07-1997
		EP 0495673 A1	22-07-1992
		JP 4309341 A	30-10-1992
		US 5250058 A	05-10-1993
		ZA 9200328 A	16-07-1993